

10/558277  
IAP15 Rec'd PCT/PTO 23 NOV 2005

Docket No.: 02420/100M850-US1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Catherine Clelland et al.

Application No.: Not Yet Assigned

Confirmation No.: N/A

Filed: Concurrently Herewith

Art Unit: N/A

For: SURROGATE CELL GENE EXPRESSION  
SIGNATURES FOR EVALUATING THE  
PHYSICAL STATE OF A SUBJECT

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement accompanies the new patent application submitted herewith.

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application as required by 37 CFR 1.98(a)(2)(i), amended October 2004, as the U.S. Patent and Trademark Office has waived this requirement for all U.S. patent applications. Applicant submits herewith copies of foreign and non-patents in accordance with 37 CFR 1.98(a)(2).

Application No.: Not Yet Assigned

2

Docket No.: 02420/100M850-US1

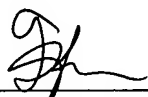
In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: November 23, 2005

Respectfully submitted,

By  *Howard M. Frankfort*  
(53,970)  
Howard M. Frankfort, Ph.D.  
Registration No.: 32,613  
DARBY & DARBY P.C.  
P.O. Box 5257  
New York, New York 10150-5257  
(212) 527-7700  
(212) 527-7701 (Fax)  
Attorneys/Agents For Applicant

10/558277

IAP15 Rec'd PCT/PTO 23 NOV 2005

PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Catherine Clelland
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	5	Attorney Docket Number	02420/100M850-US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA*	US-5,578,832	11-26-1996	Trulson et al.	
	AB*	US-5,556,752	09-17-1996	Lockhart et al.	
	AC*	US-5,510,270	04-23-1996	Fodor et al.	
	AD*	US-5,539,083	07-23-1996	Cook et al.	
	AE*	US-6,190,857	02-20-2001	Ralph et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup>	Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	Kim DK, <i>et al.</i> Neuropsychopharmacology 2001;25(1):84-90	
	CB	DeMattos RB, <i>et al.</i> , Science 2002, 295:2264-2267	
	CC	Ilani <i>et al.</i> Proc Natl Acad Sci U S A 2001;98(2):625-8	
	CD	Cole <i>et al.</i> , Nat Genet. 1999; 21(1 Suppl):38-41.	
	CE	Golub <i>et al.</i> , Science 1999; 286(5439):531-7	
	CF	Alizadeh <i>et al.</i> , Nature 2000; 403(6769):503-11	
	CG	Perou <i>et al.</i> , Nature 2000; 406(6797):747-52	
	CH	Bittner <i>et al.</i> , Nature 2000; 406(6795):536-40	
	CI	Dhanasekaran <i>et al.</i> , Nature 2001; 412(6849):822-6	
	CJ	Luo <i>et al.</i> , Mol Carcinog 2002; 33(1):25-35	
	CK	Nature 2002 ;415(6871):530-6	
	CL	Assersohn <i>et al.</i> , Clin Cancer Res. 2002; 8(3):794-801	
	CM	Ensolì & Sirianni., Crit Rev Oncog 1998; 9(2):107-24	
	CN	O'Byrne & Dagleish, Br J Cancer 2001;85(4):473-83	
	CO	Kono <i>et al.</i> , Clin Cancer Res. 1996; 2(11):1825-8	
	CP	Oliver and Nouri., Cancer Surv. 1992; 173-204	
	CQ	Lopez <i>et al.</i> , Cell Immunol. 1998; 190(2):141-55	
	CR	Elsasser-Beile <i>et al.</i> , J. Cancer Res Clin Oncol. 1993; 119(7):430-3	
	CS	Veltri <i>et al.</i> , Urology 1999; 53(1):139-47	
	CT	Strom <i>et al.</i> , Prostate 2001; 1;47(4):269-75	
	CU	Nakashima <i>et al.</i> , Cancer Res. 2000; 6(7):2702-6	
	CV	Filella <i>et al.</i> , Prostate 2000; 44(4):271-4	
	CW	De Vita <i>et al.</i> , Oncol Rep. 2000; 7(2):357-61	
	CX	O'Donovan <i>et al.</i> , Am J Hum Genet 1999;65, 587-592	
Examiner Signature			Date Considered

10/558277

IAP15 Rec'd PCT/PTO 20 NOV 2005

PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Catherine Clelland
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	5	Attorney Docket Number	02420/100M850-US1

	CY	Blackshaw et al., Cell 2001;107:579-89
	CZ	Oestreich et al., Pharmacogenomics J. 2001; 1(4):272-87
	CA1	Li et al., Hum Mol Genet. 2004 13(6):609-16
	CB1	Loring et al., DNA Cell Biol. 2001;20:683-95
	CC1	Saiki et al., Science 1988, 239:487
	CD1	Shuey et al. Drug Discov Today. 2002 7(20):1040-6
	CE1	Dorsett et al. Nat Rev Drug Discov. 2004 3(4):318-29
	CF1	Xu et al., Biochem Biophys Res Commun. 2004 316(3):680-7
	CG1	Devroe et al., Expert Opin Biol Ther. 2004 4(3):319-27
	CH1	Davidson et al., Lancet Neurol. 2004 (3):145-9
	CI1	Sambrook et al., supra, 9.50-9.51
	CJ1	Sambrook et al., supra, 11.7-11.8
	CK1	Shalon et al., Genome Research 1996, 639-645
	CL1	Chee et al., Science 1996, 274:610-614
	CM1	Schena et al. (Proc. Natl. Acad. Sci. USA; 1996, 93:10614
	CN1	Shena et al., Science 1995, 270:467-470
	CO1	Froehler et al., Nucleic Acid Res. 1986, 14:5399-5407
	CP1	McBride et al., Tetrahedron Lett. 1983, 24:245-248
	CQ1	Egholm et al., Nature 1993, 365:566-568
	CR1	Nguyen et al., Genomics 1995, 29:207-209
	CS1	DeRisi et al., Nature Genetics 1996, 14:457-460
	CT1	Fodor et al., Science 1991, 251:767-773
	CU1	Pease et al., Proc. Natl. Acad. Sci. USA 1994, 91:5022-5026
	CV1	Lockhart et al., Nature Biotech. 1996, 14:1675
	CW1	Blanchard et al., Biosensors & Bioelectronics 1996, 11:687-90
	CX1	Maskos and Southern, Nuc. Acids Res. 1992, 20:1679-1684
	CY1	Sambrook et al., Molecular Cloning--A Laboratory Manual (2nd Ed.), Vol. 1-3, Cold Spring Harbor Laboratory, Cold Spring Harbor, N.Y., 1989
	CZ1	Chirgwin et al., Biochemistry 1979, 18:5294-5299
	CA2	Krug and Berger, Methods Enzymol. 1987, 152:316-325
	CB2	Kricka, 1992, Nonisotopic DNA Probe Techniques, Academic Press San Diego, CA
	CC2	Zhao et al., Gene 1995, 156:207-213
	CD2	Pietu et al., Genome Res. 1996, 6:492-503
	CE2	Tijssen, 1993, Hybridization With Nucleic Acid Probes, Elsevier Science Publishers B.V
	CF2	Ferguson et al., Nature Biotech. 1996, 14:1681-1684
	CG2	Slamon et al., Science. 1987;9:235(4785):177-82
	CH2	Willsher et al., Breast Cancer Res Treat. 1996; 40(3):251-5
	CI2	Draghici et al., Drug Discov Today 2002; 7(11):S55-S63
	CJ2	Akiyama. Schizophr Res 1999;37(1), 97-106
	CK2	Kim, et al., Biol Psychiatry 1998;43(9):701-4
	CL2	Sperner-Unterweger et al., Schizophr Res 1999; 38(1):61-70
	CM2	Muller et al., Am J Psychiatry 1999;156(4):634-6
	CN2	Cazzullo et al., Schizophr Res 1998 31(1):49-55
	CO2	Naudin et al., Schizophr Res 1997 26(2-3):227-33
	CP2	Greenlee et al., CA Cancer J Clin. 2000; 50(1):7-33
	CQ2	Oesterling et al., JAMA 1993; 270(7):860-4
	CR2	Seaman et al., Urol Clin North Am.; 1993; 20(4):653-63
	CS2	Catalona et al., Urology 2000; 56(2):255-260

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

10/558277

IAP15 Rec'd PCT/PTO 23 NOV 2005

PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Catherine Clelland
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	3	of	5	Attorney Docket Number	02420/100M850-US1

CT2.	Roberts <i>et al.</i> , Urology. 2000;56(5):817-22	
CU2	Bangma <i>et al.</i> , J Urol. 1997;157(6):2191-6;	
CV2	Smith <i>et al.</i> , Cancer. 1997;80(9):1852-6	
CW2	Neal <i>et al.</i> , Eur J Cancer 2000; 36(10):1316-21	
CX2	Murphy <i>et al.</i> , Cancer. 1998;83(11):2259-69	
CY2	Beckett <i>et al.</i> , Clin Cancer Res. 1999;5(12):4034-40	
CZ2	Olsson CA. Urol Clin North Am. 1997;24(2):367-78	
CA3	Lee <i>et al.</i> , Prostate 1999;39(3):213-8	
CB3	Noguchi <i>et al.</i> Int J Urol 1999;6:7-12	
CC3	O'Dowd <i>et al.</i> , Urology. 2000;55(4):553-9	
CD3	Amler <i>et al.</i> , Cancer Res. 2000; 60(21):6134-41	
CE3	Cole <i>et al.</i> (Nat Genet. 1999; 21(1 Suppl):38-41	
CF3	Schena <i>et al.</i> , Trends Biotechnol. 1999; 16(7):301-6	
CG3	Yeang <i>et al.</i> , Bioinformatics. 2001;17 Suppl 1:S316-22	
CH3	Thalmann <i>et al.</i> , Cancer Res. 1999; 54(10):2577-81.	
CI3	Chen <i>et al.</i> , J Cell Biol 2000; 151:1321-36	
CJ3	Elmore <i>et al.</i> , N Engl J Med. 1998;338(16):1089-96	
CK3	Berois <i>et al.</i> , Eur J Cancer 2000; 36(6):717-23	
CL3	<i>et al.</i> , Int J Cancer. 1998;79(1):23-6	
CM3	<i>et al.</i> , Proc Natl Acad Sci USA; 98(5):2646-51	
CN3	Lopez-Otin & Diamandis Endocr Rev. 19(4):365-96	
CO3	Statist. Sincia. 2000; 12, 111-139	
CP3	Yang <i>et al.</i> , Nat Rev Genet. 2002; 3(8):579-88	
CQ3	Simon <i>et al.</i> , Genet Epidemiol. 2002; 23(1):21-36	
CR3	Van t'Veer <i>et al.</i> , Nature 2002;415(6871):530-6	
CS3	Spleiss <i>et al.</i> , Mol Psychiatry 1998; 3,512-20	
CT3	Tsai <i>et al.</i> , J Affect Disord 2001; 64,185-93	
CU3	Cloninger <i>et al.</i> , Am. J. Med. Genet. 1998; 81,275-281	
CV3	Kinney <i>et al.</i> , J Affect Disord 1998; 50,117-24	
CW3	Gunduz <i>et al.</i> , Schizophr Res. 1999; 40,237-433	
CX3	Sorlie <i>et al.</i> , Proc Natl Acad Sci U S A 2001; 98,10869-74	
CY3	Colantuoni <i>et al.</i> , Neurobiol Dis. 2001; 8,847-65	
CZ3	Mirnic <i>et al.</i> , Trends Neurosci. 2001; 24,479-86	
CA4	Kwak <i>et al.</i> , BMC Med Genet. 2001; 2(1):3	
CB4	Joyce <i>et al.</i> , Ann N Y Acad Sci. 1999; 877,595-613	
CC4	Guillen <i>et al.</i> , Nature 2001; 411,86-9	
CD4	Barbanti <i>et al.</i> , Mech Ageing Dev 2000; 120,65-75	
CE4	Eur J Immunol. 2001; 31,3504-12	
CF4	Nemanov <i>et al.</i> , Int J Neuropsychopharmacol. 1999; 2,25-29	
CG4	Lin <i>et al.</i> , Schizophr Res. 1998; 32(1), 9-15	
CH4	Ann Neurol. 2001; 50,699-707	
CI4	Hakak <i>et al.</i> , Proc. Natl Acad Sci U.S.A. 2001; 98: 4746-51	
CJ4	Ramaswamy <i>et al.</i> , Proc Natl Acad Sci U S A 2001;98(26):15149-54	
CK4	Overall <i>et al.</i> , Psychol Rep. 1962; 10,799-812	
CL4	Folstein . J Psychiat Res. 1975, 12,189-198	
CM4	Eisen <i>et al.</i> , Proc Natl Acad Sci. 1998; 95(25):14863-8	
CN4	Muller <i>et al.</i> , Eur Arch Psychiatry Clin Neurosci 1997; 247: 308-13	
CO4	Andreassen <i>et al.</i> , Br J Psychiatry 1989; Suppl (7), 49-58. 89)	
CP4	Andreassen <i>et al.</i> , Psychopathology 1995; 28: 7-17	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Catherine Clelland
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	4	of	5	Attorney Docket Number	02420/100M850-US1

	CQ4	Katzman <i>et al.</i> , (2001) In Iqbal, K., Sisdia, S.S., and Winblad, B. (eds), Alzheimer's Disease: Advances in Etiology, Pathogenesis and Therapeutics. John Wiley and Sons, Ltd. Chichester, England, pp. 11-21	
	CR4	Ewbank <i>et al.</i> , Am J Public Health 1999; 89: 90-92	
	CS4	Tandon <i>et al.</i> , Genome Biol. Reviews 2002; 3: 3014.1-3014.9	
	CT4	Farrer <i>et al.</i> , JAMA 1997; 278: 1349-56	
	CU4	Galasko <i>et al.</i> , Arch Neurol 1994; 51: 888-95	
	CV4	Chui <i>et al.</i> , Neurology 1997; 49: 925-35	
	CW4	Bookheimer <i>et al.</i> , N Eng J Med 2000; 343: 450-6	
	CX4	Munzar <i>et al.</i> , Neurol Clin Neurophysiol 2002; 2002: 2-8	
	CY4	Mayeux <i>et al.</i> , Ann Neurol 1999; 46: 412-16	
	CZ4	Feldman <i>et al.</i> , J Alzheimers Dis 2001; 3: 507-516	
	CA5	Biochem Biophys Res Comm 2001; 284: 310-16	
	CB5	J Neurosci Res 2002; 70: 462-473	
	CC5	Neurology 2000; 54: 1297-1304	
	CD5	Armstrong <i>et al.</i> , Nat Genetics 2002; 30: 41-47	
	CE5	Lewis <i>et al.</i> , Am. J. Hum. Genet. 2003; 73: 34-48	
	CF5	Whittemore <i>et al.</i> , Am J Epidemiol. 1995, 141, 732-40	
	CG5	Easton <i>et al.</i> , The Prostate, 57: 261-269, 2003	
	CH5	Janer <i>et al.</i> , The Prostate, 57: 309-319, 2003	
	CI5	Brown <i>et al.</i> , Brit J. Cancer, 90: 510-514, 2004	
	CJ5	Witte <i>et al.</i> , The Prostate, 57: 298-308, 2003	
	CK5	Cunningham <i>et al.</i> , The Prostate, 57: 335-346, 2003	
	CL5	Verhage <i>et al.</i> , Familial Cancer, 2: 57-67, 2003	
	CM5	Carpten <i>et al.</i> , Nat Genet, 30: 181-184, 2002	
	CN5	Tavtigian-SV., Nat Genet, 27: 172-180, 2001	
	CO5	Gibbs <i>et al.</i> , Am J Hum Genet, 64: 776-787, 1999	
	CP5	Abdul and Hoosein, Cancer Letters, 186: 99-105, 2002	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--